



UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

oh

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/441,875	11/17/99	CHARLTON	D CWP-012CN3
------------	----------	----------	--------------

021323 HM22/0521
TESTA, HURWITZ & THIBEAULT, LLP
HIGH STREET TOWER
125 HIGH STREET
BOSTON MA 02110

EXAMINER

DO, F

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

7
05/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/441,875

Applicant(s)

Charlton et al.

Examiner

Pens T. D

Art Unit

1641



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Jan 18, 2001

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 27-39 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 27-39 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All. b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) ☐ Other: _____

Art Unit: 1641

DETAILED ACTION

Amendment Entry

1. The preliminary amendment filed on January 18, 2001 has been acknowledged and entered.

Drawings

2. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on January 18, 2001 have been accepted.

Withdrawn Rejections

3. Rejections under 35 U.S.C. 112, 2nd paragraph are withdrawn herein.
4. Rejection under 35 U.S.C. 102(b) for claims 14-26 is withdrawn herein.
5. Rejection under 35 U.S.C. 101 (statutory type double patenting) is withdrawn herein.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 U.S.C. § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 27-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown, III et al. (EP 217 403 A2).

Art Unit: 1641

Brown has a test device (10) comprising a casing (14) defining a sample inlet and viewing window (fluid chamber 7) and having disposed therein a test strip comprising a porous fiber matrix 12 (equates the sorbent material which defines a flow path for transporting the liquid sample therealong from a sample contact region to a test site and a control site) and a test site (34) comprising an immobilized first protein to a ligand, and a control site (32) comprising immobilized second protein (i.e. an immobilized binder which binds to the conjugate, which conjugate binds to the ligand), and a filter means (22), which device is useful for competitive, sandwich and indirect assays. Chorionic gonadotropin is an explicitly illustrated ligand (example 3). Particles coated with first protein are immobilized within the porous fiber matrix 12 (see col. 4, line 49-col. 5, line 2). The first protein and second protein consists of a variety of monoclonal antibodies or polyclonal antibodies. (See col. 5, lines 54-56). The sorbent means 20 disposed in the casing 14 is for absorbing excess fluid during the use of the assay device. The absorbent means 20 comprises one or more layers of material and is in physical contact with the barrier material 18, when used, or with the reaction matrix 12. (See col. 10, lines 29-46).

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CAR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

Art Unit: 1641

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CAR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CAR 3.73(b).

9. Claims 27-39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 5,989,921. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '921 are broad enough to read on those of the invention. The device of the invention differs from that of '921 because it does not have a casing. One of ordinary skill in the art would find it obvious to successfully perform the assay using the device of '921 without a casing.

Response to Arguments

10. Applicant's arguments filed February 27, 2001 have been fully considered but they are not persuasive.

Regarding the 102(b) rejection by Brown, III et al. for claims 14-26, applicant submits that the invention is directed to a test device which comprises a test strip (defined as a long, narrow piece of material) and the test strip comprises a sorbent material that permits lateral flow from a sample contact region to a test site and a control site. Applicant argues that Brown fails to teach a test strip as a long, narrow piece of material which permits lateral flow from the sample contact region to a test site and a control site. Applicant also argues that Brown fails to disclose colored particulate material.

Art Unit: 1641

A test strip, regardless of size and shape, has one unique function, that is to transport materials such as fluid sample. Since Brown's disk-shaped test strip performs the same function, it inherently reads on the test strip of the invention. Furthermore, applicant fails to describe the specific shape of the claimed test strip in the specification. One skilled in the art would be able to vary the size and shape of the test strip according to his/her preference without alternating the functions of the test strip. The sorbent material of Brown does not equate the sorbent material of the invention. Rather, the porous fiber reaction matrix is the claimed sorbent material. Responding to the argument that Brown lacks the teaching of lateral flow, Brown teaches that particles coated with first protein and immobilized second protein are on the reaction matrix. Inherently, the test site and the control site must be in lateral flow communication. Regarding the argument about the colored particles, since Brown teaches a viewing window and particulate labels (particles coated with first protein), the reference inherently reads on colored particles as being used as labels for the assay.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MEP. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 1641

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is (703) 308-4398. The examiner can normally be reached on Mon-Fri. from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641

Pensee T. Do
Patent Examiner
May 7, 2001